UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,783	04/21/2005	Hans Schreier	05/063	6308

30608 7590 12/16/2008

GUDRUN E. HUCKETT DRAUDT
SCHUBERTSTR. 15A
WUPPERTAL, 42289
GERMANY

EXAMINER	
LAM, ANN Y	
ART UNIT	PAPER NUMBER
1641	
MAIL DATE	DELIVERY MODE
12/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,783	SCHREIER ET AL.	
	Examiner	Art Unit	
	ANN Y. LAM	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colman et al., 5,665,065, in view of Fodor et al., 6,309,822.

Colman et al. teach a medication infusion device comprising a compact programmable medication infusion pump adapted to receive and support a syringe carrying a prescribed medication such as insulin. The pump further includes a sensor or meter for detecting or receiving a current patient parameter, such as a blood glucose reading. The parameter sensor or meter provides a data input to the pump controller for altering the medication delivery protocol in an appropriate manner. In accordance with the invention, the altered protocol can be automatically implemented, but may in the alternative be recommended to the patient by means of the visual display for convenient acceptance or rejection by manipulation of one or more of the control buttons, or otherwise overridden entirely by the patient in favor of a different or modified delivery protocol. See column 2, lines 46-64.

Colman et al. further teach that in an alternative embodiment, the medication infusion device comprises a manually operated syringe-type implement, such as a

medication delivery pen. The delivery pen includes a manually adjustable dial or the like for retracting a syringe plunger through a predetermined stroke, in association with a visual display which indicates the medication dosage to be delivered. The delivery pen includes a controller which receives a patient parameter input from a sensor or meter, such as a current blood glucose reading. The controller responds to the data input representing the patient parameter to recommend a dispensing protocol which can be accepted or modified by the patient. See column 2, line 65 – col. 3, line 11. A glucose sensor or meter 16' such as a built-in sensor for receiving and reading a glucose test strip, provides a data input to the delivery pen 10'. An internal controller responds to the data input to provide a recommended medication dispensing protocol via the display 26'. The patient may operate the dial 42 and plunger 44 to deliver the recommended dosage. See column 5, lines 15-40.

Colman et al. further describes that a pump controller 24 responds to a data input from the glucose sensor or meter 16, in addition to manually inputted instructions by means of the buttons 22. The glucose sensor or meter 16 is conveniently mounted directly onto the pump housing 18 in a readily accessible position, depending upon the type of glucose sensor or meter used. See column 5, lines 41-60.

As to claim 8, the Colman et al. medicine dispenser is equivalent to the claimed dosimeter containing a medicament. The dosimeter, such as the delivery pen, is considered a chip, and it comprises a dispensing means to dispense the medicine. The Colman et al. sensor is equivalent to the claimed diagnostic indicator system comprising a detector, wherein the dosimeter and the diagnostic indicator system are

interconnected and information regarding the dosage is supplied to the dosimeter for dispensing the medicament in accordance with the information regarding the dosage.

However, Colman et al. do not disclose that the sensor is for detection of a genetic property that is determined by gene expression testing.

It is noted, however, that while the exemplary embodiments disclosed by Colman et al. refer to the sensor as a glucose sensor, the disclosed invention is not limited to glucose sensing or infusion of insulin. This is repeated throughout the disclosure, in which the invention is disclosed generically and discloses blood glucose reading as an example for the sensor, and insulin as an example of medication. For instance, in column 2, lines 33-37, it is disclosed that the "improved medication infusion device includes data input pertaining to a current patient condition parameter, such as a current blood glucose reading, and responds thereto to provide an appropriate medication delivery protocol for the patient" (emphasis added). In column 3, lines 46-49, it is disclosed that "the medication infusion device comprises a compact programmable medication infusion pump adapted to receive and support a syringe carrying a prescribed medication such as insulin". In column 3, lines 6-11, it is disclosed that the invention may comprise a delivery pen in association with a visual display which indicates the medication dosage to be delivered upon subsequent plunger advancement, and that the "delivery pen includes a controller which receives a patient parameter input from a sensor or meter, such as a current blood glucose reading". In column 3, lines 49-58, it is disclosed that in the exemplary drawings, a

medication infusion device such as a programmable infusion pump is designed for programmable delivery of a selected medication such as insulin...."

Thus , the exemplary embodiments disclose a glucose sensor as the specific type of sensor, and it is understood that the invention is useful with regulating insulin delivery based on blood glucose level as well as other parameters since the improvement of the invention relates to the ability to enter other parameters that affect the medication requirement, such as current patient activity, eating schedules, etc., as would be desirable for determining the appropriate insulin delivery (col. 2, lines 37-45.) However, as shown above, it is understood that the invention is not limited to use for blood glucose level detection nor for delivery of insulin. Thus it is suggested that the invention can be modified to detect other desirable diagnostic indicators of a medical condition, and can be used to deliver the medicine appropriate for that medical condition. In any case, the skilled artisan would have recognized that the general teachings of Colman et al. of a combination device comprising a diagnostic device and medical delivery device can be modified to diagnose and deliver various known medical conditions and medicines, respectively. Thus, the skilled artisan would look to other diagnostic sensors and medicines in the art, such as the Fodor et al. patent.

It is disclosed by Fodor et al. that where the expression levels of a disease marker (e.g., P53, RTK, or HER2) are to be detected (e.g, for the diagnosis of a pathological condition in a patient), comparison of the expression levels of the disease marker in the sample to disease markers from a healthy organism will reveal any

deviations in the expression levels of the marker in the test sample as compared to the healthy sample. Correlation of such deviations with a pathological condition provides a diagnostic assay for that condition. See column 43, lines 24-32.

For example, a blood sample is used for diagnosing any of a number of different physiological conditions. A multi-dimensional fingerprinting method could become a routine means for diagnosing an enormous number of physiological features simultaneously. This provides information on an enormous number of parameters together at one time. The genetic predisposition provides a physician with the ability to predict the likelihood of particular medical conditions arising at any particular moment. It also provides the ability to apply preventive medicine. See column 89, lines 49-63.

Fodor et al. also disclose a microarray suggested for use in performing the diagnostic assays. The microarray is formed on a substrate and contains identical or distinct biopolymers (col. 94, lines 53-61.) The microarray substrate may includes cells formed by the grid lines and the underlying backing are water-impermeable, having side barriers projecting above, and thus defined-volume samples can be placed in each well without risk of cross-contamination with sample material in adjacent cells (col. 95, lines 62-67.) Simultaneous assays are conducted by exposure of the array to the assay reagents, including any necessary detection reagents, and then analyzed using standard detection means (col. 96, lines 28-41.) It is taught that the gridded support can also be used for non-DNA ELISA assays (col. 98, lines 28-35), and can be used for screening assays in medical diagnostics (col. 98, lines 36-42), and allows for rapid and convenient screening on the same solid support (col. 98, lines 43-51.) It is

noted that Fodor et al. also disclose kits with compartments with the desired necessary reagents, e.g., substrate, labeling reagents for target samples, buffers, and other useful accompanying products. See column 90, lines 4-9.

The skilled artisan would have combined the teachings of Colman et al. and Fodor et al. for the following reasons. As described above, the Colman et al. apparatus comprise a combination of a medicine dispenser and a diagnostic sensor, wherein the sensor provides data for recommending a dispensing protocol. While the exemplary embodiments and one particularly useful purpose of the invention relates to sensing blood glucose and dispensing insulin, Colman et al. refer to these as examples throughout the patent, and thus the skilled artisan would understand that the invention is not limited to detecting blood glucose, nor to dispensing insulin. The skilled artisan would have recognized the benefits of utilizing such teachings for diagnosis of other medical conditions and having readily available an attached medicine dispensing device, as taught by Colman et al., to treat those medical conditions. Thus it would have been within the skills of the ordinary artisan to tailor the Colman et al. teachings for diagnosis and treatment of various known medical conditions, such as those disclosed by Fodor et al. (e.g., detecting the expression levels of a disease marker (e.g., P53, RTK, or HER2) for the diagnosis of a pathological condition in a patient), and dispensing any appropriate medication. The skilled artisan would have reasonable expectation of success since Colman et al. suggest a combination of a sensor and a dispenser of therapeutic agents for metering the appropriate amount of medicine, without limiting the structure of device or its elements, and thus the skilled artisan

would have reasonable expectation of success in combining known detector elements as suggested by Fodor et al. with a medicine dispensing device, as suggested by Colman et al.

As to claim 9, Fodor et al. disclose that the multi cell substrate contains a porous surface within each cell (col. 94, lines 53-61.)

As to claim 10, Fodor et al. disclose use of detection labels (col. 96, lines 28-41, and col. 90, lines 4-9) [which provides information visually.]

As to claim 11, a dispenser for individual dosing is disclosed by Colman et al. as has been discussed above.

As to claim 12, the dispenser as disclosed by Colman et al. as discussed above allows for individually adjusting therapy in accordance with a physiological or pathological state of a patient.

As to claim 13, the device is capable of providing simple and unequivocal handling by the patient or nurse or physician.

As to claim 14, in the modification of the Colman et al. invention, the diagnostic indicator system as suggested by Fodor et al. is considered a chip (specifically a gene expression chip, since it detects gene expression.)

Response to Arguments

Applicant's arguments with respect to claims 8-13 have been considered but are moot in view of the new ground(s) of rejection as necessitated by the amendments.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641